Attachment H
Reply to deficiency

APR 19 2006

510(k) Summary
21 CFR 807.92

Date: 3/28/06

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR part 807.92.

1. **Company making the submission:**

Company Name:	Byrne Medical, Inc.
Address:	2021 Airport Road, Conroe, TX 77301
Telephone:	(936) 539-0391
	(936) 639-0393 Fax
Contact:	Christopher Meador
e-mail:	cmeador@byrnemedical.com

2. **Device:**

Proprietary Name:	EndoGator Endoscopy Irrigation Pump
Common Name:	Endoscopy Irrigation Pump
Classification Name:	Endoscope and/or Accessories

3. **Predicate Devices:**

Meditron Endolav Model EL-100, K882048, Xylog Corp., 83 Hobart St, Hackensack, NJ 07601

4. **Classifications Names & Citations**:

21 CFR 876.1500, Class II, KOG, Gastroenterology and Urology.

5. **Description:**

The Byrne Medical, Inc., EndoGator Endoscopy Irrigation Pump is used for Endoscopic irrigation for use with washing catheters integral endoscope water jet channels and endoscope working channels.

The EGP-100 pump will provide an adjustable flow-rate from 0-550ml/min, which is based on a variable motor RPM. The motor is controlled by the use of a potentiometer and control dial. A foot pedal activated air switch controls the running or stopping of the pump motor and a peristaltic pump head. These parts will not cause contamination of sterile water during deliverance.

6. Indications for Use:

Endoscopic irrigation for use with washing catheters integral endoscope water jet channels and endoscope working channels.

7. Contra-indications:

None noted at the time of this submission.

8. Comparison:

The general method of operation and construction between the predicate device and the Byrne Medical, Inc., EndoGator pump is simulator. Indications for use are the same for both devices.

The Byrne Medical, Inc., EndoGator pump is smaller and the weight is less.

Specifications comparison:

Parameter	EndoGator EGP-100 ***This Submission***	Meditron Endovav EL-100 K882048	Parameter is the same
Indications for Use	Endoscopic irrigation for use with washing catheters, integral endoscope water jet channels, and endoscope working channels.	Endoscopic irrigation for use with washing catheters, integral endoscope water jet channels, and endoscope working channels.	Yes
Regulation #	21 CFR 876.1500	21 CFR 876.1500	Yes
Target Population	Male/Female pediatric to adult	Male/Female pediatric to adult	Yes
Prescription Device	Yes	Yes	Yes
Dimensions (H x W xD)	3.5" x 6" x 8"	4.5" x 5" x 8"	No
Classification	Class I, Type BF, Ordinary Equipment for Continuous operation	Class I, Type BF, Ordinary Equipment for Continuous operation	Yes
Min and Max flow rate	Min – 0 ml/min Max – 550 ml/min	Min – 15 ml/min Max – 650 ml/min	No
Pressure	Min – 0 PSI Max – 48 PSI	Min – 2 PSI Max – 40 PSI	No
Pump type	Peristaltic	Peristaltic	Yes

9. Test Review:

The EMI and Safety Testing shall be conducted and meet specified acceptance criteria before the device is marketed.

Conclusions:

The conclusion drawn from this comparison, together with required passage of electromagnetic compatibility and safety testing, is that the Byrne Medical, Inc. EndoGator pump is equivalent in safety and efficacy to its predicated device.

Christopher Meador
Regulatory Affairs and Quality Control Manager

Date: 3/28/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Byrne Medical, Inc.
c/o Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices and
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

APR 19 2006

Re: K060962
Trade/Device Name: EndoGator Model # EGP-100
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: April 6, 2006
Received: April 7, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment C
Reply to deficiencies

Indications for Use Statement

510(k) Number K060962

Device Name: **EndoGator Model # EGP-100**

Indications for Use: Endoscopic irrigation for use with washing catheters integral endoscope water jet channels and endoscope working channels.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Kaufman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060962